IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
Charlottesville Division

THE MILLER FIRM, LLC
108 Railroad Avenue
Orange, Virginia 22960

Plaintiff/Complainant,

Civil Action No:

vs.

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Defendant/Respondent.

COMPLAINT FOR INJUNCTIVE RELIEF

Complainant, THE MILLER FIRM, LLC, files this Complaint For Injunctive Relief pursuant to the Freedom of Information Act, 5 U.S.C. § 552(4)(B), and states as follows.

I.

PARTIES

1. Complainant The Miller Firm, LLC is a Virginia limited liability corporation with its principal place of business in Orange, Virginia. Complainant primarily represents people injured after taking prescription drugs.

2. Respondent Food and Drug Administration is an agency of the Executive Branch of the United States government. It is an agency within the meaning of 5 U.S.C. § 552(f).

II.

Jurisdiction and Venue

3. This Court has jurisdiction over this action, and venue is proper, pursuant to 5 U.S.C. § 552 (4)(B) because Complainant has its principal place of business within the Western District of Virginia.

III.

Background

4. Complainant law firm represents more than 200 consumers who took Actos (pioglitazone), an anti-diabetic drug manufactured, marketed and sold by Takeda Pharmaceuticals North America, Inc.("Takeda").

5. Subsequent to FDA approval of Actos, it has become widely accepted in the academic and scientific community that pioglitazone substantially increases the risk of bladder cancer. Takeda's internal discussion of epidemiology data reveals that the related increase is as high as 400%. Each of Complainant's aforementioned clients has been diagnosed with bladder cancer after taking Actos.

6. Many of these clients continue to suffer from Actos-related cancer, which has metastasized in some cases, and others have succumbed to the disease.

7. Logic dictates that many more thousands of diabetes patients in the United States continue to take Actos or face the potential of being prescribed Actos.

8. Takeda had substantial notice of the risk of bladder cancer as early as 1996. For many years, however, Takeda downplayed the cancer risk both to the public and to the FDA.

9. The final New Drug Application (NDA) for Actos was submitted to the FDA in January 1999. There followed many years of correspondence between the FDA and Takeda regarding Actos.

10. Dr. Jeri El Hage is a former FDA employee who served as a toxicologist investigating the effects of pioglitazone on bladder development. Takeda interacted with Dr. El Hage extensively on the subject of Actos' carcinogenetic properties.

11. Dr. El Hage recommended that Takeda update the Actos label in 2002 to include a stronger reference to bladder cancer, and expressed doubt about Takeda's "crystal hypothesis," a theory advanced by the company suggesting bladder cancer in rat subjects bore no relevance for humans.

12. In 2003, the FDA directed Takeda to strengthen and clarify its reference to possible carcinogenesis in the drug's label. It was not until 2011 that Takeda amended the Actos label to notify users of the risk of bladder cancer. However, the current label remains inadequate as it does nothing to quantify the risk and therefore the prescriber or user remain unable to weigh potential risks and benefits.

IV.

Procedural Facts

13. On or about June 19, 2012, Complainant sent to the FDA a FOIA request ("Request 2012-4699") seeking:

Correspondence: Any and all documents, electronic mail, e-mails, correspondence and memoranda prepared by, prepared for, directed to, or received by Dr. Jeri El-Hage relating or referring to Pioglitazone (Actos).

(Letter attached hereto as Exhibit A).

14. On June 28, 2012, the FDA responded that it would "respond as soon as possible." (Exhibit B).

15. Thereafter, Complainant had several phone conversations with FDA employees, including Guru Udapi, regarding the document production. These employees informed Complainant that the backlog for FOIA requests was more than 12 months. The FDA refused to make any accommodations to Complainant regarding the requests. It refused to explore implementation of rolling document production.

16. The FDA has made no claim of privilege over any of the requested documents nor suggested that any of the information was not disclosable under the Freedom of Information Act.

17. On or about August 7, 2012, Complainant requested that the FDA handle Request 2012-4699 on an expedited basis, citing a compelling need for the information (Exhibit C).

18. To date, Complainant has received no response to its request for expedited processing.

19. To date, no documents responsive 2012-4699 have been produced to Complainant in any form.

IV.

Standard of Review

20. When the FDA "does not respond to a FOIA request in accordance with the time period specified by statute, the requester may seek judicial review 'to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld.'" *Caretolive v. U.S. Food and Drug Administration*, 2008 U.S.Dist. LEXIS 41393 (2008), *quoting* 5 U.S.C. § 552(a)(4)(B).

21. The district courts are to review agency decisions, "including those regarding expedited processing of FOIA requests," *de novo*. *Caretolive, supra;* 5 U.S.C. § 552(a)(4)(B).

V.

INJUNCTION

22. Pursuant to 5 U.S.C. § 552(a)(6)(E)(i), federal agencies must expedite processing of requests for records when the requestor "demonstrates a compelling need."

23. 21 CFR 20.44 states that such a need exists when:

A failure to obtain the information expedited basis "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual."

24. That regulation further requires that the FDA "will determine whether to grant a request for expedited processing within 10 days of receipt."

25. FDA has violated 21 CFR 20.44 by failing to notify Complainant of a decision regarding expedited processing within the prescribed 10 days. Therefore, the FDA has waived any opposition or objection to the requests for expedited processing.

26. In the alternative, by its inaction and silence, the FDA has in effect denied the requests for expedited processing. Due to the lack of response, however, Complainant is unable to "appeal the agency's decision by writing to the official identified in the denial letter," as contemplated by 21 CFR 20.44(h). Therefore, Complainant has fully exhausted the administrative remedies available.

27. Expedited processing of these Requests is necessary to the health and safety of a large number of diabetes patients in America. Furthermore, it is necessary to the health and safety of the more than 200 clients represented by the Complainant law firm.

28. As a result of Takeda's failure to disclose the potential for bladder cancer, many thousands of Actos takers have developed bladder cancer. Many of these patients have died; many more still remain ignorant of the causal relationship between their diabetes medication and their cancer.

29. Many physicians, too, remain unaware of the nature and extent of the bladder cancer link. They continue to prescribe Actos to diabetes patients, and may newly prescribe the drug to future patients.

30. Though the FDA approved and Takeda instituted a label change in 2011 making reference to bladder cancer, the warning is woefully inadequate. The dissemination of substantive information on the risk is absolutely necessary to the masses of diabetes sufferers in order to prevent many more cases of bladder cancer and death.

31. With respect to the Complainant's individual clients, it is fair to say that they have become aware, to some extent, of the link between Actos and cancer. But, the undersigned attorneys do not make health care decisions on behalf of their clients. Facing incomplete information at this time, there is a grave potential that one or more of these people will continue to use Actos to their detriment.

32. Documentation in possession of the Respondent will shed crucial light on the relationship between Actos and cancer. Users and potential users, in possession of such information, will be able to make informed decisions about their health care. Complainant anticipates that access to such information will result in a decrease in bladder cancer cases and deaths nationwide.

33. Dissemination of this information is particularly time-sensitive and merits expedited processing of the Requests. Takeda's own study, while downplaying the risk,

acknowledged a "significant increase in the relative hazard of bladder cancer with more than 24 months of exposure."[1]

34. The release of the requested information on an expedited basis has the potential to save thousands of lives. Such a delay as proposed by the FDA could result in many current Actos users taking the drug for such a duration that it leads to cancer, though they are presently cancer-free.

35. Though the FDA undoubtedly receives a large number of FOIA requests, the lives of many current and future diabetes patients depend on the release of further information on Actos in an expedient manner.

36. As Justice Brandeis noted, "publicity is justly commended as a remedy for social and industrial diseases."[2] In the present circumstances, the disinfecting nature of sunlight has the potential to prevent a disease even more injurious and concrete than those social and industrial ills.

VI.
Prayer for Relief

WHEREFORE, Complainant prays that this Court:

1. Order the FDA to disclose the requested records, in their entirety, on an expedited basis, within 10 days;
2. Award Complainant its costs and reasonable attorneys' fees incurred in this action; and
3. Grant such other relief as the Court may deem just and proper.

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[1] Lewis, James *et al.* Risk of Bladder Cancer Among Diabetic Patients Treated with Pioglitazone*, Diabetes Care* (2001); 34: 916-922.

[2] Brandeis, Louis. *Other People's Money – and How Bankers Use It.* (1914).

Respectfully Submitted by:

/s/ Jeffrey A. Travers

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